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| APPLICATION NO.  | FILING DATE | FIRST-NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/670,046   | 09/24/2003  | Frank Hardt          | RO0233US.CON (#90568)        | 5022             |
| 28672 7590 05/01/2007<br>D. PETER HOCHBERG CO. L.P.A.<br>1940 EAST 6TH STREET<br>CLEVELAND, OH 44114 |             |                      | EXAMINER<br>ZIRKER, DANIEL R |                  |
|  |             |                      | ART UNIT                     | PAPER NUMBER     |
|  |             |                      | 1771                         |                  |
|  |             |                      | MAIL DATE                    | DELIVERY MODE    |
|  |             |                      | 05/01/2007                   | PAPER            |

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The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/670,046  
Filing Date: September 24, 2003  
Appellant(s): HARDT ET AL.

**MAILED**  
**MAY 01 2007**  
**GROUP 1700**

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D. Peter Hochberg  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed December 29, 2006 appealing from the  
Office action mailed November 8, 2005

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.  
It is noted that there is only one independent claim, claim 1, and that while dependent claims 2 and 6-8 are selectively summarized they have not been argued.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. However it should be noted that it is claims 1-8 which are rejected under 35 USC 103(a) as being unpatentable over Kreckel et al.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,244,677                      Kreckel et al                      9-1993

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1) Claims 1-8 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants regard as the invention. More particularly, appellants' earlier amendment to claim 1 that "the matrix layer being a compacted material" is believed to be vague, indefinite and confusing since the specification contains no teachings (with the cancellation of former claim 9) as to just what constitutes a "compacted material". Note that in Paragraph [0031] the specification recites only that the matrix material can be a "compacted material, foam, fabric, porous sheet, nonwoven fabric, etc." which unfortunately provides no guidance as to what a "compacted material" can comprise. Note also that now cancelled claim 9 taught that a compacted material suitable for use could, however, be any one of the last four embodiments. Accordingly, one of ordinary skill can only guess as to just what a suitable "compacted material" is, since although the Examiner does not deny that the term "compacted material" is known in the dictionary there are also many embodiments which are clearly nonoperative. The specification, however, provides no additional guidance as regards this issue.

2) Claims 1-8 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention. More particularly, as was described in the preceding grounds of rejection the specification in its present form is believed to shed no light as to just what embodiments constitute a suitable "compacted material". Note again that cancelled claim 9 taught that a compacted material could be selected from the group consisting of a foam, a fabric, a porous sheet or a non-woven fabric, but in the specification the only discussion of what a compacted material is can be found in Paragraph [0031] which teaches only the equivalence of a "compacted material" with any of the four embodiments which were also set forth in the Markush grouping of cancelled claim 9. Note also that while the Examiner does not contest the fact that "compacted materials" are known in the literature (as is evidenced by appellants' recently provided citations, etc.) the fact also remains that many other "compacted materials" such as, e.g. many crushed or compacted elements, are also clearly non operative.

3) Claims 1-8 are rejected under 35 USC 103(a) as being unpatentable over Kreckel et al. The reference discloses (note particularly the Figures, particularly Figs. 4 and 2, Col 1, lines 9-18, Col 4, line 59-Col 5, line 38) substantially an anticipation in certain embodiments of the claimed adhesive die cut article of claim 1, disclosing an adhesive punchout article comprising an adhesive layer with an inner recess or reservoir 5, the outer line of the adhesive article sharing no common point with the outer line of the internal cutout. As such, as shown particularly in Figure 4 having a release sheet 4, adhesive 3, foam layer 2 and reservoir cutout 5, the reference clearly discloses an adhesive backed transdermal medicine delivery die cut bandage for application to

the skin. The reference is not an anticipation because it fails to disclose for claim 1 the presence of any specific pharmaceutical active ingredients, such as those compositions specifically claimed by appellants, as well as failing to at least expressly disclose a "compacted material" for a matrix material. The Examiner, however, believes that the presence of almost any suitable pharmaceutical active ingredient would be an obvious modification to one of ordinary skill, as the record todate clearly lacks any sort of unexpected results being shown, and further notes that the reference discloses foams which are taught by the specification as being functional equivalents to the claimed compacted material.

#### **(10) Response to Argument**

The Examiner would like to make the following observations with respect to the various arguments submitted by appellants. As regards the 112, 2<sup>nd</sup> paragraph rejection of record it is noted (Brief, pages 11-12) that the issue is not whether "compact" or "compacted" is known in the dictionary, but whether or not if appellants' assertion that it "is in no way vague or confusing to one skilled in the art" is in fact true. For example, can't foams, which the Examiner again notes were given as an example of compacted materials in original and now cancelled claim 9, be compacted? Are such embodiments as, e.g. crushed steel, which is clearly a compacted material, suitable for use? The Examiner could give many more examples besides these, but he believes that he has more than made his point that this term, without further amplification, is simply vague and indefinite with respect to setting forth the metes and bounds of the claimed invention. As regards the closely related 112, 1<sup>st</sup> paragraph rejection the

Examiner further notes that in view of the great uncertainty as to just what particular compacted materials are suitable for use the specification as regards this particular element is little more than an invitation to experiment. Furthermore, as regards appellants' contention (Brief, page 14 top paragraph) that they disagree "with the conclusion that these different materials [taught in Paragraph [0031]] for the matrix layer are intended to be equivalents" simply ignores the fact that his specification has made an admission that these materials are functional equivalents in that paragraph.

With respect to the prior art obviousness rejection based upon Kreckel et al the Examiner would first like to note that the specification is simply silent (see Paragraph [0029]) regarding the fact that the claimed pharmaceutical active ingredients and the adhesive article containing same are particularly directed towards topical treatment of certain skin disorders (Brief, page 15, 1<sup>st</sup> complete paragraph). Additionally, their related statement (Brief, page 16, 1<sup>st</sup> complete paragraph) that pores "do not exist in a compacted material" is not only not supported by any suitable authority, but it simply isn't true! Note again that Kreckel et al teaches that foams, which were originally taught by claim 9 as being a compacted material, are suitable as the matrix material, as the specification also teaches. The Examiner would like to conclude his remarks by making the observation that the specification either appears to give no meaningful guidance as to what from and how a suitable compacted material can be made or, alternatively, claim 9 before its cancellation taught that a compacted material could be, e.g. a foam material.

Art Unit: 1771

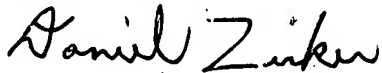
**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Daniel Zirker



Conferees:

Terrel Morris



Jennifer K. Michener